

## DATA SHEET

### Amzoate

## Sodium Benzoate Powder

**Product Code**

S08 and S08-ROW.

**Active Ingredient**

Sodium Benzoate Ph Eur.

**Description of Product**

Pure Sodium Benzoate Ph Eur powder.

**Presentation**

This product is supplied as 250 g of white crystalline or granular powder in a white plastic container with a tamper-evident closure.

**Storage**

Store below 25°C.

**Shelf Life**

Three years.

**Excipients of Known Effect**

This product is supplied as a pure powder containing no excipients.

**Free-From Information**

This product is supplied as a pure powder containing no excipients.

**Therapeutic Indications**

Sodium benzoate is used in the maintenance treatment of hyperammonaemia due to urea cycle disorders (specialist use only) and in non-ketotic hyperglycinaemia (specialist use only).<sup>1</sup> It has also been reported to be effective in reducing plasma-glycine concentrations in non-ketotic hyperglycinaemia, although it may not be effective in preventing mental retardation.<sup>2</sup>

For further information on the management of urea cycle disorders consult the British Inherited Metabolic Disease Group (BIMDG) website at: [www.bimdg.org.uk](http://www.bimdg.org.uk).

**Dosage****Maintenance treatment of hyperammonaemia due to urea cycle disorders and non-ketotic hyperglycinaemia (specialist use only):<sup>1</sup>**

By mouth:

Neonate: up to 250 mg/kg daily in 3-4 divided doses, dose to be taken with feeds.

Child: up to 250 mg/kg daily in 3-4 divided doses, dose to be taken with feeds or meals; maximum 12 g per day.

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### **Administration**

This product supplied as a pure powder which may be used as an ingredient for extemporaneous preparations for oral administration. The product may be divided into individual powders. The powder can be weighed into individual tablet bottles and dispensed to the patient. It can be mixed (until completely dissolved) and taken in water, milk or fruit juice (please note that this product is less soluble in acidic drinks).<sup>1</sup> Alternatively, the powder can be mixed into cold food and consumed immediately.

### **Contraindications and Precautions**

Hypersensitivity to sodium benzoate; respiratory reactions to sodium benzoate can occur especially in patients susceptible to aspirin induced asthma.<sup>2</sup>

Use with caution in patients with conditions involving sodium retention with edema and in those with congestive heart failure or with renal insufficiency (product contains significant amount of sodium<sup>1</sup>. 500 mg of Sodium Benzoate contains 3.5 mmol (81 mg) of sodium ions.

Use with caution in neonates with hyperbilirubinemia as benzoate competes with bilirubin binding sites on albumin, putting neonates at risk of kernicterus. Premature infants have been reported to be at risk of metabolic acidosis and kernicterus.<sup>2</sup>

### **Side-effects and Adverse Reactions**

Adverse effects of sodium benzoate include:

Anorexia; coma; irritability; lethargy; nausea; vomiting.

Gastro-intestinal side-effects may be reduced by giving smaller doses more frequently.<sup>1</sup>

Always refer to the current edition of the BNF for Children for a full list of possible adverse effects

### **Symptoms of overdose in infants include:**

Vomiting, irritability, lethargy. In more severe cases of overdose, renal tubular dysfunction, hypokalaemia, hypocalcaemia and metabolic acidosis can occur.<sup>2</sup>

### **Mode of Action**

Sodium benzoate is thought to be a metabolically active agent in which benzoate is first conjugated by coenzyme A to form benzoyl CoA, which then conjugates with glycine in liver and kidney mitochondria to form hippurate (hippuric acid, N-benzoylglycine) which in turn is rapidly excreted by the kidneys via glomerular filtration and tubular secretion. One mole of hippurate contains one mole of waste nitrogen. Thus, 1 mole of nitrogen is removed per mole of benzoate when it is conjugated with glycine (one half as much nitrogen as is excreted in urea). Thus, although not as efficient, hippurate can serve as an alternative vehicle for removal of waste nitrogen.<sup>3</sup>

### **Pharmacokinetics**

Sodium benzoate is absorbed from the gastrointestinal tract and conjugated with the amino acid glycine in the liver to form hippuric acid, which is rapidly excreted in the urine.<sup>3</sup>

### **Interactions with other Medications**

The effects of Sodium Benzoate are possibly reduced by sodium valproate, valporic acid, haloperidol and corticosteroids.<sup>1</sup>

### **Pregnancy and Breastfeeding**

No information available.

### **Legal Category**

Sodium Benzoate (Amzoate) Powder is an 'Unlicensed Medicine' within the meaning of the current legislation, governed by the Human Medicines Regulations 2012.

This publication is solely for the technical guidance of prescribers and dispensers of Sodium Benzoate (Amzoate) Powder and must not be considered as a recommendation or endorsement for the clinical use of the product. The information provided in this publication may not be exhaustive or reflective of all the information in the public domain.

**Transmissible Spongiform Encephalopathies**

All starting materials are certified as compliant with EMA/410/01 rev.3 (S.I. 2003/1680) for minimising the risk of BSE/TSE contamination.

**References:**

- 1) Paediatric Formulary Committee (2018). BNF for Children 2018-2019. London: BMJ Group, Pharmaceutical Press, and RCPCH Publications. p.614.
- 2) Brayfield A (ed), Martindale: The Complete Drug Reference. Sodium Benzoate [online] London: Pharmaceutical Press. Available from <<http://www.medicinescomplete.com/>> (accessed on 14-Mar-2019)
- 3) Misel ML, Gish RG, Patton H, Mendler M. Sodium Benzoate for Treatment of Hepatic Encephalopathy. Gastroenterology & Hepatology. 2013; 9:219-227 (available online via <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3977640/>)